Haiyan Kangyuan Medical Instrument Co.,Ltd.
Songpodong Road Shendang Town,
314311, Haiyan, Zhejiang
China.

Haiyan, 2023-03-28

Subject: MDD CE certificate validity

To whom it may concern,

This is to declare that our MDD CE Certificate issued by TüV Rheinland in accordance with Directives 93/42/EEC （HD 60121795 0001）which had expired on the 6th of August 2022 has been recognized as valid until the 31st of December 2028 automatically by the "Regulation (EU) 2023/607 amending the MDR 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices" published on the "Official Journal of the European Union" On the 20th of March 2023

We, Haiyan Kangyuan Medical Instrument Co.,Ltd.(KY), herewith declare that KY has applied to DEKRA (NB) for certification under Medical Device Regulation (EU 2017/745) ("MDR"). A Certification Agreement for the MDR conformity assessment has been signed on the 14th of December 2021.

With kind regards,

Yaling Xu
PRRC for KY

海盐康源医疗器械有限公司
HAIYAN KANGYUAN MEDICAL INSTRUMENT CO.,LTD.

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60121795 0001

Report No.: 15053499 007

Manufacturer:
Haiyan Kangyuan
Medical Instrument Co., Ltd.
Songpodong Rd., Shendang Town
Haiyan, Zhejiang 314311
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60112421 0001

Expiry Date: 2022-08-06

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-08-10

Date: 2017-08-10

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60121795 0001
Report No.: 15053499 007

Manufacturer:
Haiyan Kangyuan
Medical Instrument Co., Ltd.
Songpodong Rd., Shendang Town
Haiyan, Zhejiang 314311
China

Products:
- Urinary Catheters for Single Use (Foley)
- Suprapubic Balloon Catheters for Single Use
- Urinary Catheters for Single Use (Nelaton)
- Endotracheal Tubes for Single Use
- Stomach Tubes for Single Use
- Suction Catheters for Single Use
- Nebulizer Masks for Single Use
- Oxygen Masks for Single Use
- Nasal Oxygen Cannula for Single Use
- Guedel Airways for Single Use
- Laryngeal Mask Airways
- Silicone Foley Catheters with Temperature Probe for Single Use
- Breathing Circuits for Single Use
- Suction Connection Tubes for Single Use
- Anesthesia Masks for Single Use
- Breathing Filters for Single Use
- Suction-Evacuation Access Sheath for Single Use
- Silicone Foley Catheters with Tiemann Tip for Single Use

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

X Ren

Date: 2017-08-10